

Skirboll, Lana (OD)

From: McClure, Michael (NICHD)
Sent: Monday, November 02, 1998 2:45 PM
To: Skirboll, Lana (OD)
Subject: RE: Human Embryo Derived Pluripotent Cell Lines/ GERON Corp.

Importance: High

Lana:

Have not seen the informed consent forms. They may or may not provide them if asked but usually do. They don't provide them for grants unless asked and they haven't been asked to do so yet. If this doesn't involve grants, they could decline pro-forma.

It did go through the local IRB at the University of WISCONSIN prior to the research being done (pg. 10-11 of Press Info backgrounder). But was this for the companies project or a university project? This has different ramifications depending on which. They also had an independent (external member) ethics advisory board formed to watch over the "company" project (pg. 14-15 of backgrounder). They also adopted the NIH Human Embryo Research Panel guidelines in that bodies report (pg. 14-15).

Thompson's work in the primate and other animal models is/has been funded by NIH - primarily NICHD and NCRR. This site is/was the first one that raised the specific question of shared NIH equipment use for animal and human embryo research that we discussed in our earlier meetings. Unless we were to do a "field visit" inspection to determine whether the human work was done in separate facilities with separate equipment at separate sites (either in Wisconsin or California as non-NIH mixed resources) we will never know whether the lab facilities were shared and were an issue. They were clearly warned via mail and e-mail that separation was absolutely necessary. The findings on equipment title vestment and the university role in disposition via GPS guidelines was provided to them at that early point, for example. If this work was done using any of the NCRR primate core facilities or NIH grant funded lab facilities, there is a real potential for a problem in my opinion.

If they used NIH resources, I doubt it could have been inadvertently.

Mike McClure/NICHD